

Overview of CANNRA and Regulatory Work Related to Product Safety

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Disclosures

I do not have any external funding sources to disclose and do not take funding from the pharmaceutical, alcohol, tobacco, or cannabis industries.

While this presentation highlights some of the current regulatory work related to lab testing and product safety, the findings in this presentation do not represent an official position of CANNRA or of any of our individual member states.

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Agenda

- Brief overview of CANNRA
- Policy context
- Cannabis lab testing in U.S. states
 - Lay of the land and challenges
 - Brief overview of CANNRA Lab Testing Committee and related work
- Other challenges to consumer safety and regulation
 - Hemp-derived products
- Conclusions

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CANNRA Overview

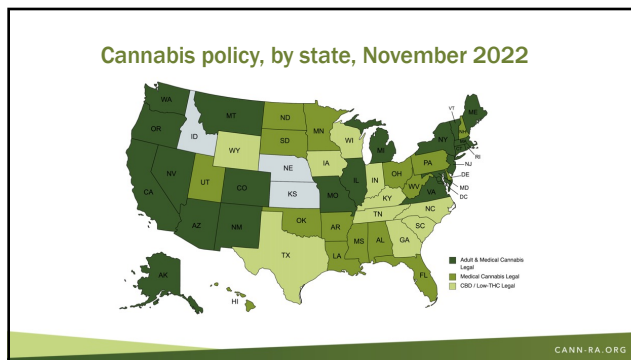
- A national nonpartisan organization that convenes, educates, and supports government agencies engaged in cannabis regulation or policy implementation.
- >40 member states and U.S. territories
- Not an advocacy group; **takes no formal position for or against cannabis legalization.**
- 12 different active special committees on varied cannabis policy topics.
- Funded primarily by member agencies; no non-governmental membership.
- An affiliate of the Council of State Governments (CSG).

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The challenge of our terminology...

"Medical" vs. "Recreational"

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Timeline of Adult Use Cannabis Legalization, by State

State	Year adult use legalization passed	Ballot measure (% support) OR legislative passage	Date retail marketplace opened (opens)
CO	2012	Ballot measure (55%)	January 2014
WA	2012	Ballot measure (56%)	July 2014
OR	2014	Ballot measure (56%)	October 2015 (through medical dispensaries)
AK	2014	Ballot measure (53%)	October 2016
DC	2014	Ballot measure (55%)	No retail marketplace approved
CA	2016	Ballot measure (56%)	January 2018
ME	2016	Ballot measure (50%)	October 2020 (through medical dispensaries)
MA	2016	Ballot measure (54%)	November 2018
NV	2016	Ballot measure (54%)	July 2017 (through medical dispensaries)
VT	2018	Legislative	Expected late 2022
MI	2018	Ballot measure (56%)	December 2019
IL	2019	Legislative	January 2020 (through medical dispensaries)
AZ	2020	Ballot measure (60%)	January 2021 (through medical dispensaries)
MT	2020	Ballot measure (57%)	January 2022 (through medical dispensaries)
ND	2020	Ballot measure (67%)	April 2022
SD	2020	Ballot measure (54%)	Legislation overturned by legal challenge
NY	2021	Legislative	Expected 2022 (or later)
VA	2021	Legislative	Expected 2024
NM	2021	Legislative	April 2022
CT	2021	Legislative	Expected 2022 (or later)
RI	2022	Legislative	Expected 2022 (through medical dispensaries)
MO	2022	Ballot measure (53%)	Expected early in 2023
MD	2022	Ballot measure (67%)	Expected in 2023

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What do regulated cannabis markets look like?

- Regulation through: Departments of health, revenue, consumer protection, alcohol/beverage control boards, or stand-alone regulatory agencies
- Licensed entities that grow, process, and sell cannabis
 - For adult use, adult-only retail stores that sell cannabis and cannabis products
- Regulations for:
 - Product safety, ingredients, and product testing
 - Packaging and labeling
 - Advertising
 - Point of sale environment
 - Inspections and compliance
- Public education and stakeholder engagement
- Data monitoring
- Frequent changes to policy and procedures – even in established states

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Product Types and Forms

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Product ingredients & product composition

Additives:

- Diluents & excipients
- Terpenes (cannabis-derived, botanical, synthetic)
- Generally not highly regulated

Policy levers:

- Thresholds for additives
- Full ingredient disclosure
- GRAS requirements (for foods)
- FDA inactive ingredient list (for drugs)

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Lab Testing Overview

- **Required testing?**
 - Non-Medical: All require testing by licensed third-party labs
 - Medical: Required in most states (but not all)
 - Lab accreditation (e.g., ISO/IEC 17025) required in most states
- **Reference lab?**
 - Exists or in progress in CA, CO, LA, NY, OK, MI...
- **Sampling and testing procedures:**
 - Sampling approaches vary as does timing of testing.
 - Most states batch testing; some doing finished product testing. About half states w/authority for post-market testing.
- **Testing requirements:**
 - Vary by state (with most testing for microbial contamination, residual solvents, metals, pesticides, and cannabinoid content).

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Sample of Lab Testing Variation across Non-Medical States

Table 5. Adult use cannabis contaminant testing requirements, by state, as of January 2021*

State	Cannabinoid concentration	Residual solvents	Microbials (bacterial/fungal)	Yeasts/molds	Mycotoxins	Water activity	Styrene/butadiene	Heavy metals	Pesticides/Chemical residue	Foreign matter
AK	X	X	X					X		
CA	X	X	X	X	X	X	X	X	X	X
CO	X	X	X	X	X	X	X	X	X	X
IL	X	X	X	X	X	X	X	X	X	
MA	X	X	X	X	X	X	X	X	X	
ME	X	P	X	X	X		X	P	P	X
MI	X	X	X	X	X	X	X	X	X	X
NV	X	X	X	X	X	X	X	X	X	X
OR	X	X	X	X	X	X	X	P	X	X
WA	X	X	X	X	X	X	X	X		

*In many states, testing requirements vary somewhat across different product types (eg. inhalable, infused, concentrate). AK - Alaska, CA - California, CO - Colorado, IL - Illinois, MA - Massachusetts, ME - Maine, MI - Michigan, NY - Nevada, OR - Oregon, P - Prohibit or Prohibit, WA - Washington State.

Source: Schauer, G.L. (2021) Cannabis Policy in the United States: Implications for Public Health. *J Natl Cancer Inst Monogr* 2021;(58):sgae026.

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Lab-related challenges in states

- Short timeframe to develop rules (and lab testing approaches)
- Laboratories:
 - State lab engagement challenges due to Schedule 1 status
 - Third party testing approach (lab shopping, variation across labs, etc.)
 - Development of a reference lab is rare, but a focus of a number of states
- Testing:
 - Sampling and process validation varies across states
 - Contaminants, cannabinoids, additives (what can/should you test for?)
 - Testing methods and protocols across different contaminants and product mediums
 - Policy regulations that are ahead of lab methods
- What to do with test results (e.g., contamination)? When are results meaningful for public health? What remediation to allow and what additional testing to require?

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Testing Accuracy and Issues



Industry Insiders Warn of Fraud at Marijuana Testing Labs

By Nick Raposo, Michael Ball, Mark Fitzsimons and Michael Kahan - Published November 16, 2021 - Updated on December 16, 2021 at 11:27 am

Pot testing lab fudged numbers about marijuana potency, Washington board says

By Christopher Hill - Updated December 16, 2021

False test results, lab shopping put cannabis consumers at risk

By Roger Brown - November 8, 2021 - Updated December 16, 2021

Lab Shopping: Highlighting the Need for Checks and Balances in Cannabis

By [unreadable]

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Product oversight, compliance, and monitoring

- Pre-market:
 - Required testing
 - Product preapproval processes
 - Packaging review processes
- Post-market:
 - Point-of-sale education
 - Compliance checks
 - Post-market testing authority
- Throughout:
 - Seed to sale tracking -> can link to patient and provider registries

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Other helpful efforts for states

- Publication of methods (e.g., AOAC, ASTM, USP methods)
- Support to "on board" new methods as they become available
- Training to ensure that labs are validating methods appropriately to determine competency
- Training to ensure that lab inspectors understand ISO 17025 and have the scientific expertise to inspect labs for compliance
- Regulatory staff with laboratory, microbiology, and chemistry expertise

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A few words about hemp-derived products in the US....



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Process for chemically deriving cannabinoids....

HEMP → CBD EXTRACT + ACIDS, HEAT, SOLVENTS → OTHER CANNABINOIDS
(Delta-8, Delta-10, HHC, THCO, THCP, THCv, THCH, THCd, 11-HO-THC, etc.)

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THC isomers and Novel Cannabinoids

Consumer Safety concerns:

- Not subjected to the same packaging, labeling requirements
- Not subjected to the same testing requirements
 - Some new cannabinoid products have no data from use in humans
 - Potentially dangerous manufacturing
 - Unknown byproducts
- Widely available in retail outlets and online → widely available to youth
- May undermine adult use markets

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New data underscores risks of adulterants, byproducts, and metals

Novel Δ⁸-Tetrahydrocannabinol Vaporizers Contain Unlabeled Adulterants, Unintended Byproducts of Chemical Synthesis, and Heavy Metals
Chen Hui, Chen Hui, Saito 2022, 16, 11-16

Vaping Cannabinoid Acetates Leads to Ketene Formation
Karlito B. Mungai, Robert P. Jensen, Robert M. Strongin

The Dark Side of Cannabinoids: The Unanticipated Social and Clinical Implications of Synthetic Δ⁸-THC
Karlito B. Mungai, Robert P. Jensen, Robert M. Strongin

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Licit vs. illicit markets

- Tested, regulated products
- Adult only sales environment
- Childproof packaging
- Labeling
- Recall abilities
- Some regulation over ingredients
- Public education opportunities

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CANNRA Lab Testing Committee

- Committee is co-chaired by technical experts from states
- Proficiency Testing Subcommittee**
 - Working on an internal CANNRA White paper on best practice recommendations for establishing cannabis testing laboratories.
 - Potency testing and lab shopping have been frequently discussed
- Lab Testing Standardization Subcommittee**
 - Focused on chemistry, microbiology, quality assurance, and sampling
- Emerging Trends and Issues Subcommittee**
 - Have discussed a range of topics including growth regulators, new technologies in distillation, synthetic cannabinoids, and setting up reference laboratories.

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Closing thoughts and summary

- CANNRA exists to facilitate discussion amongst states about cannabis regulations, best practices, differences across governmental programs regulating cannabis.
- CANNRA has been extremely active in discussing lab testing and consumer safety issues.
- States face a range of challenges related to lab testing.
- States vary in their testing approaches – these differences can require legislative action to change/modify.
- There are areas where organizations like ASTM, USP, AOAC and others have and can support states.
- The current U.S. federal approach to hemp-derived products and novel cannabinoids poses a threat to consumer safety – regulations around lab testing are warranted.

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